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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/763,646      | 07/09/2001  | Klaus Urich          | VI/98-023.DE        | 7684             |

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EXAMINER

SERKE, CATHERINE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3763     | 8            |

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |   |
|------------------------------|-----------------|--------------|---|
| <b>Office Action Summary</b> | Application No. | Applicant(s) | M |
|                              | 09/763,646      | URICH, KLAUS |   |
| Examiner                     | Art Unit        |              |   |
| Catherine Serke              | 3763            |              |   |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-111 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 91-99 and 101-103 is/are allowed.

6) Claim(s) 1-15, 17-27, 32-47, 49-58, 62-72, 77-86, 100 and 104-108 is/are rejected.

7) Claim(s) 16, 28-31, 48, 59-61, 73-76, 87-90 and 109-111 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The “movement mechanism”, “means for mounting a syringe” and “means cooperable” have not been defined by the specification. The examiner reminds applicant that when evoking means plus function, the recitations must be in the form of means plus function language which does not include structural language. Additionally, all the structural elements of the means plus function language must be clearly defined by the specification.

### ***Claim Objections***

Claims 16,31 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternate form. See MPEP § 608.01(n). Accordingly, the claim 31 not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 26, 42, 58, 71, 85, 100 and 108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 26, 42, 58, 71, 85 and 108 recite the limitation "the axis". There is insufficient antecedent basis for this limitation in the claim. One cannot discern which element "the axis" is in reference to. It is recommended that "a axis" be positively recited and claimed in reference to a structural element of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15, 34-42, 45-47 and 49-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenwald (US '670).

Rosenwald discloses a body (2) comprising a distal discharge end (15), a plunger (13), and at least one agitation element (14) disposed within the body between the plunger and the distal discharge end. The device also has a recess (13b,12) in the plunger and the body of the syringe. The agitation element may be constructed from steel (density greater than fluid) or be a gas since all fluids contain dissolved gas. Regarding the functional language in the claims, as long as the prior art meets the structural limitations of the claims and is capable of performing the recited function then the prior art reads on the claims. Specifically, an user of the device is a movement mechanism that can move the device in rotational, circular or linear patterns. The body is capable of containing a ultrasound contrast agent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9,11-12,17-25,27,32-41,43-44,62-70,72,77-84,86 and 104-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al ('858) in view of Griffiths et al ('623).

Reilly discloses an injector (27) for contrast media having means for mounting (23) a syringe (22) having a body, a distal discharge end, and means cooperable (22f) with the means for mounting. The device also includes a movement mechanism (the user inserting the syringe into the injector) operably associated with the injector. As the user inserts the syringe into the injector, the user must move the syringe in both a linear and rotational path to align and fix the syringe to the injector. The method steps are considered inherent in order for the device to function as disclosed.

Reilly meets the claim limitations as described but fails to specifically teach having an agitation element within the body of the syringe. However, Griffiths discloses an apparatus and method for controlling contrast enhanced imaging that includes a syringe, injector, means for attaching and a contrast agent that includes agitation elements in the form of microbubbles, microspheres with rigid shells filled with gas or liquid, liposomes with shells, solid microparticles and other compositions (see 3:33+). The contrast agents are used with a variety of energies beamed into the body.

At the time of the invention, it would have been obvious to incorporate the contrast media of Griffiths into the invention of Reilly since both systems are analogous in the art. Since the devices are analogous a combination is proper. Additionally, the motivation for making a combination would have been in order to provide the device of Reilly with a contrast media adaptable for use with a variety of energies thereby enhancing the device's applications.

***Allowable Subject Matter***

Claims 91-99 and 101-103 are allowed.

Claim 100 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 28-30, 48, 59-61, 73-76, 87-90 and 109-111 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 26, 71, 85 and 108 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat# 5,108,927 discloses an analogous invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke   
September 29, 2002



BRIAN L. CASLER  
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